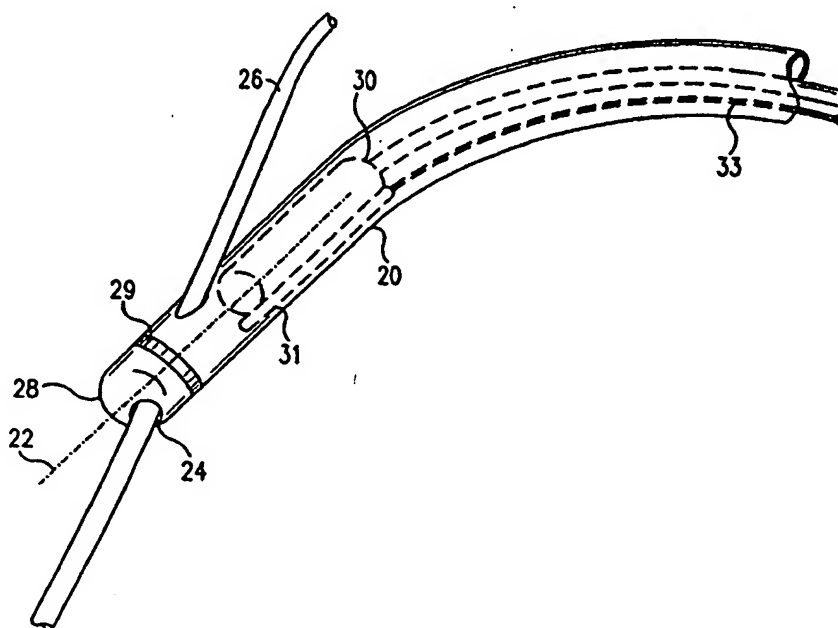




## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>6</sup> : <b>A61M 25/01</b>	<b>A1</b>	(11) International Publication Number: <b>WO 98/52637</b> (43) International Publication Date: 26 November 1998 (26.11.98)
(21) International Application Number: PCT/US98/10581 (22) International Filing Date: 22 May 1998 (22.05.98) (30) Priority Data: 60/047,512           23 May 1997 (23.05.97)      US Not furnished       21 May 1998 (21.05.98)      US (71) Applicant: BIOSENSE, INC. [US/US]; Suite 283, 9360 Sunset Drive, Miami, FL 33173 (US). (72) Inventors: ZILBERSTEIN, Joel; Zerubavel Street 13, 34671 Haifa (IL). YARON, Uri; Hrakefet Street 16, 30900 Zichron-Yaacov (IL). (74) Agents: CIAMPORCERO, Audley, A., Jr. et al.; Johnson & Johnson, One Johnson & Johnson Plaza, New Brunswick, NJ 08933 (US).	(81) Designated States: AU, BR, CA, IL, JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published With international search report.	

(54) Title: CATHETER WITH OBLIQUE LUMEN



## (57) Abstract

A flexible elongate probe (20) having a longitudinal axis (22) and a distal end (28), the probe enclosing and defining a lumen (24) for receiving and riding over a guide wire (26), characterized in that the lumen is located other than along the longitudinal axis. Preferably, the lumen passes through the probe obliquely with respect to the longitudinal axis, adjacent to the distal end of the probe. Preferably, the probe includes a sensor (30) adjacent its distal end and a deflection mechanism (31) for deflecting the distal end of the probe after withdrawal of the guide wire.

**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon			PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

## CATHETER WITH OBLIQUE LUMEN

### RELATED APPLICATIONS

5 This application claims the benefit of U.S. Provisional Patent Application no. 60/047,512, which is assigned to the assignee of the present patent application and is incorporated herein by reference.

### FIELD OF THE INVENTION

10 The present invention relates to catheters and catheterization techniques generally.

### BACKGROUND OF THE INVENTION

15 Catheters used in interventional cardiology and other applications are typically guided to a desired location in a human body, most commonly the left ventricle or other chamber of the heart, by first inserting a guide wire to the location and then sliding the catheter over the guide wire. The use of the guide  
20 wire generally shortens the time required to get the catheter into the ventricle and eases the potentially dangerous passage through the aortic valve, when entering the left ventricle. Although it is also well known in the art to insert a catheter into the heart

- 2 -

without the use of a guide wire, many cardiologists do not have the requisite level of skill or time to perform this operation, and are deterred by the risk of complications associated with such insertion.

5 Catheters for guide wire insertion are normally constructed with an open central lumen, running along the catheter's longitudinal axis, to receive the guide wire. This constructional constraint severely restricts the size and shape of functional elements within the  
10 catheter and complicates the catheter's design. Such catheters cannot generally be manipulated within the heart after insertion therein. They are therefore substantially restricted to making measurements or performing interventional procedures only at the site  
15 within the heart to which the guide wire has been inserted.

#### SUMMARY OF THE INVENTION

The present invention seeks to provide an improved  
20 catheter and catheterization technique which overcome limitations imposed by the prior art.

It is therefore an object of some aspects of the present invention to provide a catheter which is inserted into a body cavity, preferably a chamber of the

- 3 -

heart, using a guide wire, but may then be maneuvered with substantial freedom once inside the cavity.

It is a further object of some aspects of the present invention to provide a catheter which is inserted into the body along a guide wire, but which does not suffer from the structural and functional limitations imposed by having an open central lumen.

In preferred embodiments of the present invention, a catheter for insertion into the heart has a lumen passing therethrough for receiving a guide wire, wherein the lumen does not substantially coincide with the catheter's longitudinal axis. Preferably, the lumen runs obliquely through a distal portion of the catheter. Because the lumen is situated off the catheter's longitudinal axis, a central portion of the catheter is left clear for placement of functional elements therein, preferably including a tip deflection mechanism for controllably maneuvering the distal portion of the catheter within the heart.

To use the catheter, a guide wire is inserted into the heart, typically into the left ventricle, using catheterization techniques known in the art. The catheter is then guided into the heart by sliding the lumen in a distal direction over the guide wire. Once

- 4 -

the distal end of the catheter has reached its desired location in the heart, the guide wire is drawn back in a proximal direction, out of the heart, leaving the catheter in place. The distal end of the catheter may then be maneuvered freely within the heart, preferably using the tip deflection mechanism.

In some preferred embodiments of the present invention, the catheter includes a position sensor within the distal portion thereof. The position sensor preferably comprises one or more coils, which generate signals responsive to an externally-applied magnetic field, as described in U.S. Patent 5,391,199 or in PCT publication WO96/05768 and incorporated herein by reference. Preferably, the catheter further includes one or more electrodes on an outer surface of the distal portion, for measuring electrical activity and/or performing surgical procedures, such as electrosurgical ablation of the endocardium.

Additionally or alternatively, the catheter may include other sensors, known in the art, in or adjacent to its distal portion, for example, a pressure sensor or an ultrasound transducer. Likewise, the catheter may include other therapeutic elements, such as a waveguide for conveying radiation to the heart tissue, a channel

- 5 -

and/or tool for delivering medication to the tissue, or other elements known in the art.

It will be appreciated that catheters in accordance with the principles of the present invention share with  
5 guide wire-based catheters known in the art the advantage of rapid, safe and relatively easy insertion into the heart or other body cavity. Unlike catheters known in the art, however, catheters in accordance with the present invention may be maneuvered and navigated  
10 freely inside the body. They may thus be used in a range of diagnostic and therapeutic modalities, for example, in mapping of electrophysiological, mechanical, electromechanical and/or hemodynamic aspects of cardiac function.

15 There is thus provided, in accordance with a preferred embodiment of the present invention, a flexible elongate probe having a longitudinal axis and a distal end, the probe enclosing and defining a lumen for receiving and riding over a guide wire, characterized in  
20 that the lumen is located other than along the longitudinal axis.

There is further provided, in accordance with a preferred embodiment of the present invention, a catheterization kit including a guide wire and a

- 6 -

flexible elongate probe having a longitudinal axis and a distal end, the probe enclosing and defining a lumen for receiving and riding over the guide wire, characterized in that the lumen is located other than along the longitudinal axis.

Preferably, the lumen passes through the probe obliquely with respect to the longitudinal axis, most preferably adjacent to the distal end thereof.

Preferably, the probe includes a sensor, most preferably a position sensor, adjacent to the distal end.

Further preferably, the probe includes a deflection mechanism for deflecting the distal end of the probe.

In a preferred embodiment, the probe includes an electrode on an outer surface thereof. Preferably, the lumen passes through the electrode.

In another preferred embodiment, the probe includes a therapeutic device, preferably an ablation electrode, through which the lumen preferably passes.

Preferably, the probe is a catheter for insertion into the heart of a subject.

Additionally, in accordance with a preferred embodiment of the present invention, there is provided a catheterization technique including the steps of



- 7 -

inserting a guide wire through a body passage and sliding a flexible elongate probe, having a longitudinal axis, along the guide wire, the guide wire passing through a lumen in the probe which is located other than  
5 along the longitudinal axis thereof.

Preferably, as the catheter slides over the guide wire, the portion of the guide wire inside the catheter is inclined obliquely with respect to the longitudinal axis. Further preferably, the guide wire passes through  
10 an electrode fixed to an outer surface of the probe.

Preferably, the guide wire is withdrawn, while leaving the probe in place within the body passage, and the probe is navigated within a body cavity communicating with the body passage after withdrawal of  
15 the guide wire.

Preferably, the body cavity is mapped using the probe. Alternatively or additionally, a therapeutic procedure is performed within the body cavity using the  
20 probe.

#### BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be understood and appreciated more fully from the following detailed

- 8 -

description, taken in conjunction with the drawings in which:

Fig. 1 is a simplified illustration of a catheter and guide wire arrangement constructed and operative in accordance with a preferred embodiment of the present invention;

Fig. 2A is a sectional illustration of the catheter of Fig. 1;

Fig. 2B is a sectional illustration of a catheter, in accordance with an alternative preferred embodiment of the present invention; and

Figs. 3A-3C are simplified pictorial illustrations of intravascular catheterization using the catheter and guide wire of Fig. 1, in accordance with a preferred embodiment of the present invention.

#### DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Reference is now made to Fig. 1, which is a simplified pictorial illustration of a catheter 20 with a guide wire 26, in accordance with a preferred embodiment of the present invention. Catheter 20 has a lumen 24 for receiving guide wire 26. The lumen passes through a distal portion 28 of the catheter obliquely to the catheter's longitudinal axis 22. Alternatively, a

- 9 -

lumen for receiving the guide wire may be provided at any other suitable location or orientation which is not central to distal portion 28, such that the majority of the portion is available for location therein of functional apparatus for use in therapeutic treatment and/or diagnosis of the patient.

Such functional apparatus preferably includes elements for navigating catheter 20 within the body, as described below. Specifically, in the preferred embodiment shown in Fig. 1, catheter 20 includes a position sensor 30 and a tip deflection mechanism 31. Position sensor 30 preferably comprises one or more magnetic-field-responsive coils, as described, for example, in the above-mentioned U.S. patent 5,391,199 or PCT publication WO96/05768. Deflection mechanism 31 preferably comprises a resilient, bendable member, operated by a pull-wire 33, as described, for example, in PCT Patent Application PCT/IL98/00099, which is assigned to the assignee of the present patent application and whose disclosure is incorporated herein by reference. Alternatively or additionally, catheter 20 may include and be navigated within the body by means of any suitable position sensor and/or tip deflection mechanism known in the art.

- 10 -

Fig. 2A is a schematic, sectional illustration of distal portion 28 of catheter 20. As shown in this figure, catheter 20 preferably has a central bore 32 for accommodating sensor 30, as well as a side bore 34 for accepting deflection mechanism 31. These elements are preferably located proximally to oblique lumen 24. Further preferably, catheter 20 includes a ring electrode 29 on an outer surface of distal portion 28. Alternatively, the catheter may include a plurality of mutually-spaced electrodes, as are known in the art. These electrodes are used in sensing and mapping electrical potentials within the heart, and may also be used in therapeutic treatment of cardiac arrhythmias, as described below.

Fig. 2B is a schematic, sectional illustration of distal portion 28 of catheter 20, in accordance with an alternative preferred embodiment of the present invention. In this embodiment, in place of electrode 29, the catheter includes a dome electrode 36 over the distal portion and, preferably, a reference ring electrode 38 proximal thereto. The dome electrode provides enhanced functionality and ease of use, particularly in cardiac electrophysiological mapping and in RF ablation therapy. Oblique lumen 24 passes through

- 11 -

dome electrode 36, which has a suitable opening 37 for this purpose. In other respects, the catheter of Fig. 2B is functionally and structurally similar to that shown in Fig 2A.

5           Additionally or alternatively, catheter 20 may include functional elements of other types useful in endocardiac diagnostics and therapy, for example, pressure and/or flow sensors, an optical fiber for delivery of laser radiation, or a longitudinal lumen for  
10           suction and/or irrigation. It will be appreciated that catheters based on the principles of the present invention may generally include any type of functional or structural element that is used in catheters known in the art.

15           Figs. 3A-3C are simplified, schematic drawings showing intravascular catheterization of a subject 40 using catheter 20 and guide wire 26, in accordance with a preferred embodiment of the present invention. As shown in Fig. 3A, guide wire 26 is inserted  
20           percutaneously, preferably via femoral artery 42 of subject 40, and is directed into the subject's heart 44, typically into left ventricle 46, as in conventional intravascular catheterization. Then, as shown in Fig. 3B, catheter 20 is passed along wire 26 into the heart.

- 12 -

Alternatively, guide wire 26 may be used to insert catheter 20 into any other desired chamber of the heart, or to another suitable site in the subject's body.

Finally, as shown in Fig. 3C, guide wire 26 is withdrawn, leaving catheter 20 freely maneuverable within ventricle 46. By using deflection mechanism 31 and sensor 30, a physician can navigate distal portion 28 of catheter 20 to substantially any desired location within the ventricle. This navigation capability is particularly useful in mapping electrical and/or mechanical activity within the heart, as is known in the art and described, for example, in U.S. patent 5,568,809, which is incorporated herein by reference.

Similarly, catheter 20 may be used in therapeutic treatment of cardiac arrhythmias, preferably using electrode 29 to ablate areas of the endocardium by applying RF energy thereto, as is known in the art. Most preferably, such ablation is combined with mapping the heart's electrical activity, as described, for example, in U.S. patent 5,391,199, which is incorporated herein by reference.

Likewise, catheter 20 may be adapted for use in substantially any diagnostic or therapeutic procedure for which catheters known in the art are used, with the

- 13 -

5 advantage that catheter 20 can generally be inserted into the heart with considerably greater speed, ease and safety than non-wire-guided catheters. For example, the catheter may include an optical waveguide, coupled to a source of laser energy at the catheter's proximal end, for use in percutaneous myocardial revascularization (PMR) therapy, as described in PCT patent application PCT/IL97/00011, filed January 14, 1997, which is incorporated herein by reference, or as is otherwise known in the art.

10 Although the above preferred embodiments have been described with reference to cardiac catheterization, and specifically catheterization of left ventricle 46, it will be appreciated that catheters, endoscopes and other types of flexible medical probes may be produced and operated in accordance with the principles of the present invention for insertion into substantially any part of the heart, vasculature and other body cavities.

15 It will further be appreciated by persons skilled in the art that the present invention is not limited to what has been particularly shown and described hereinabove. Rather the scope of the present invention includes combinations and subcombinations of various

- 14 -

features and elements described and shown herein, as well as obvious variations and extensions thereof.



- 15 -

## C L A I M S

1. A flexible elongate probe having a longitudinal axis and a distal end, and having a lumen for receiving and riding over a guide wire, characterized in that the lumen is located along other than along the longitudinal axis.

2. A probe according to claim 1, wherein the probe includes a sensor adjacent to the distal end.

3. A probe according to claim 2, wherein the sensor comprises a position sensor.

4. A probe according to claim 2, wherein the sensor comprises an electrode on an outer surface of the probe.

5. A probe according to claim 1, wherein the probe comprises a deflection mechanism for deflecting the distal end of the probe.

6. A probe according to claim 1, wherein the probe includes a therapeutic device.

- 16 -

7. A probe according to claim 6, wherein the therapeutic device comprises an ablation electrode.

8. A probe according to claim 1, wherein the probe comprises a catheter for insertion into the heart of a subject.

9. A catheterization kit comprising:

a guide wire; and

a flexible elongate probe having a longitudinal axis and a distal end and having a lumen for receiving and riding over the guide wire, characterized in that the lumen is located along other than along the longitudinal axis.

10. A kit according to claim 9, wherein the probe includes a sensor adjacent to the distal end.

11. A kit according to claim 10, wherein the sensor comprises a position sensor.

12. A kit according to claim 10, wherein the sensor comprises an electrode on an outer surface of the probe.

- 17 -

13. A kit according to claim 9, wherein the probe comprises a deflection mechanism for deflecting the distal end of the catheter.

5 14. A probe according to claim 9, wherein the probe comprises a therapeutic device.

15. A probe according to claim 9, wherein the probe comprises a catheter for insertion into the heart of a  
10 subject.

16. A catheterization technique comprising the steps of:

15 inserting a guide wire through a body passage; and  
sliding a flexible elongate probe, having a longitudinal axis, along the guide wire, the guide wire passing through a lumen in the probe, said lumen located along other than along the longitudinal axis thereof.

20 17. A technique according to claim 15, wherein sliding the probe comprises sliding a probe such that the guide wire passes through an electrode fixed to an outer surface of the probe.

- 18 -

18. A technique according to claim 15, and comprising withdrawing the guide wire while leaving the probe in place within the body passage.

5        19. A technique according to claim 17, and comprising navigating the probe within a body cavity communicating with the body passage after withdrawal of the guide wire.

10       20. A technique according to claim 19, and comprising mapping the body cavity using the probe.

15       21. A technique according to claim 20, and comprising performing a therapeutic procedure within the body cavity using the probe.

1/4

FIG. 1

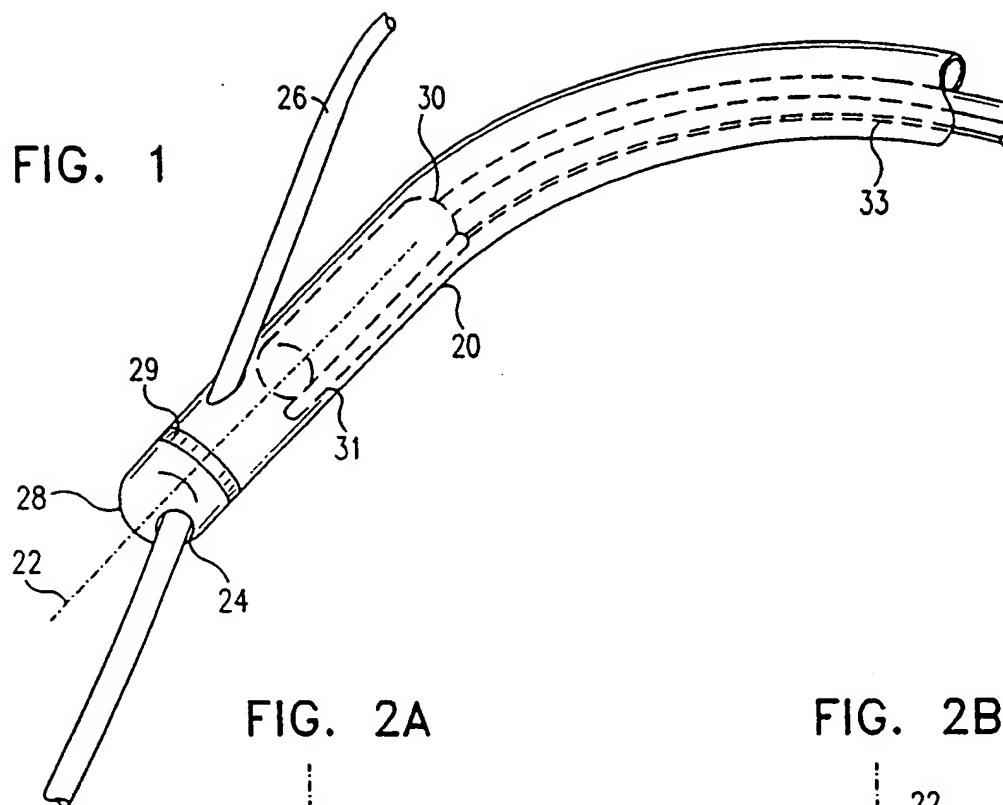


FIG. 2A

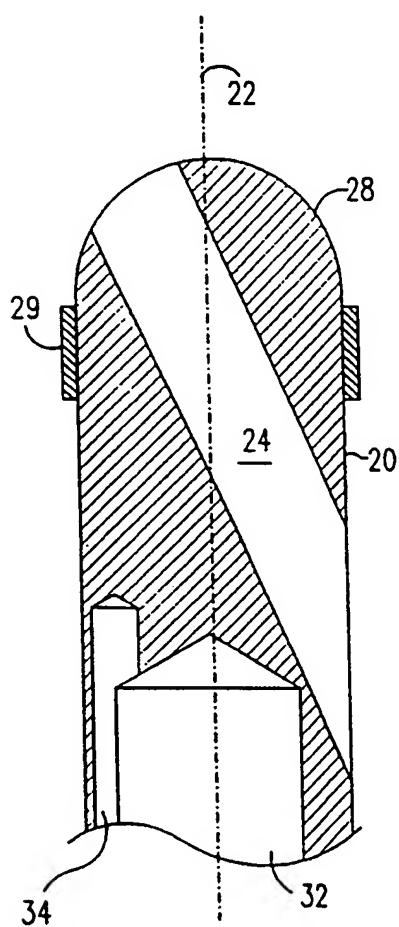
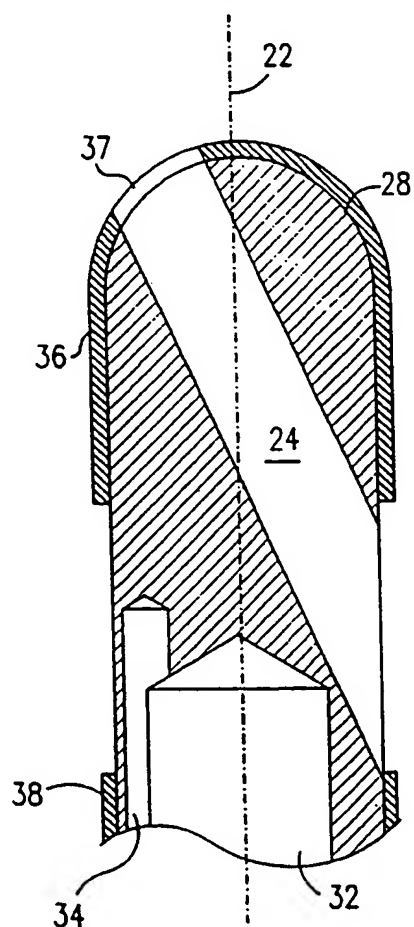
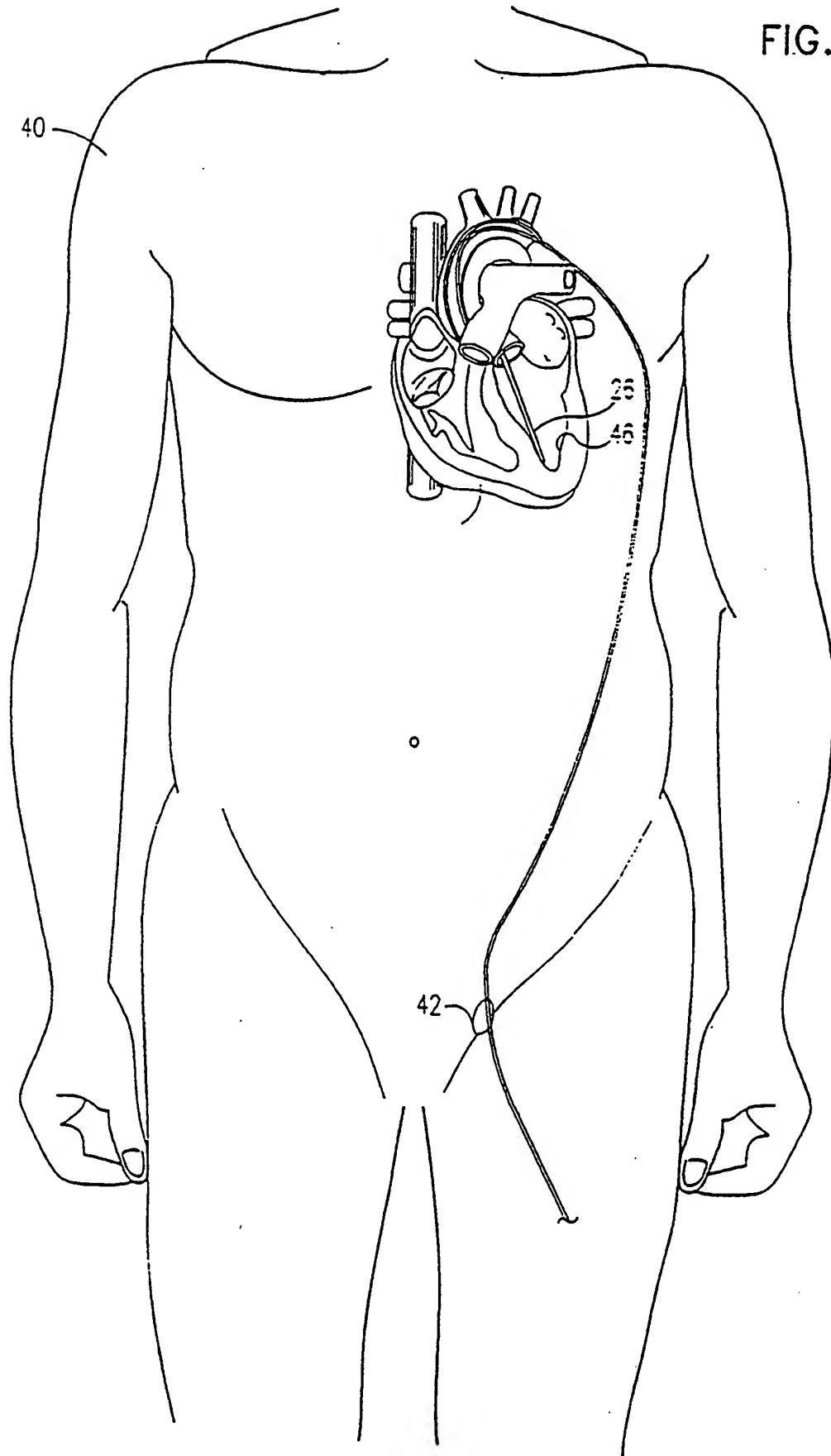


FIG. 2B



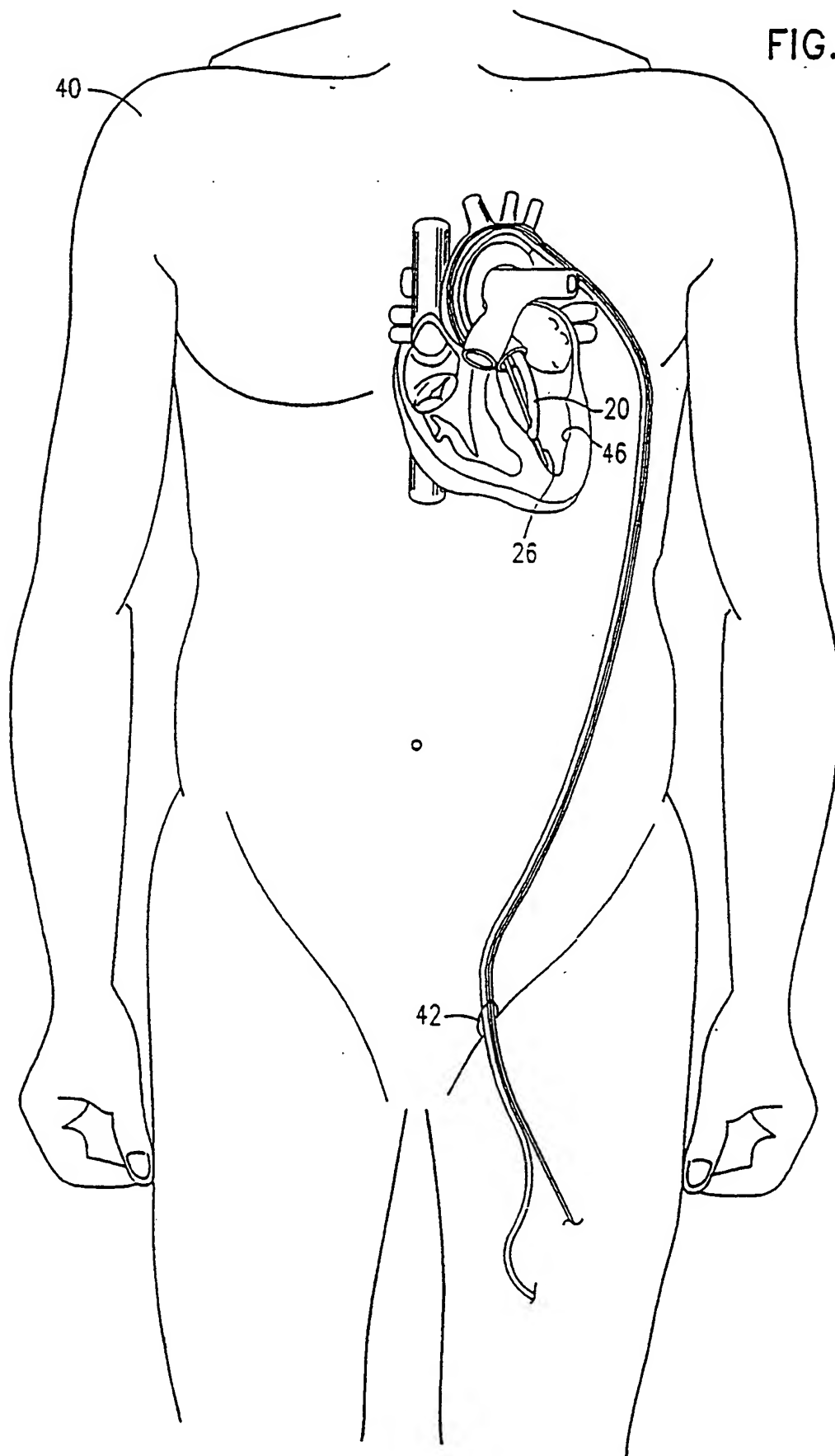
2/4

FIG. 3A



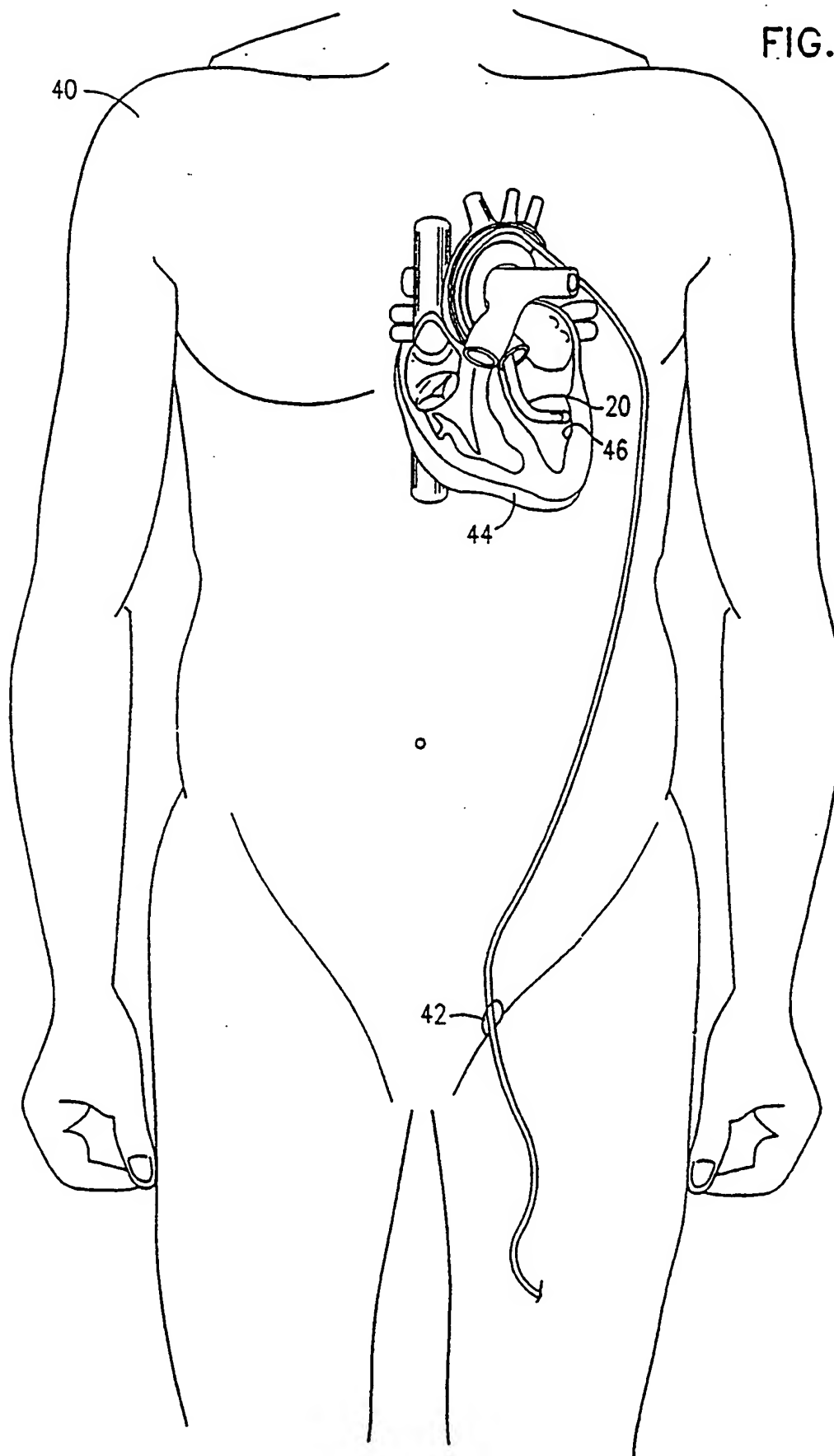
3/4

FIG. 3B



4/4

FIG. 3C





# INTERNATIONAL SEARCH REPORT

International Application No  
PCT/US 98/10581

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 6 A61M25/01

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61M A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 443 457 A (GINN) 22 August 1995 see abstract; figures ---	1,9
A	US 5 540 236 A (GINN) 30 July 1996 see abstract; figures ---	1,6,8,9, 14
A	WO 96 05768 A (BIOSENSE) 29 February 1996 cited in the application see the whole document ---	1-15
A	WO 93 15790 A (AVITALL) 19 August 1993 see abstract; figures -----	1,5-9, 13-15

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

### \* Special categories of cited documents :

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

- \*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- \*&\* document member of the same patent family

Date of the actual completion of the international search

13 August 1998

Date of mailing of the international search report

01.09.98

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Kousouretas, I

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US 98/10581

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 16-21  
because they relate to subject matter not required to be searched by this Authority, namely:  
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 98/10581

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 5443457	A	22-08-1995	CA 2184097 A	31-08-1995
			EP 0746371 A	11-12-1996
			JP 10500584 T	20-01-1998
			WO 9523007 A	31-08-1995
-----				
US 5540236	A	30-07-1996	NONE	
-----				
WO 9605768	A	29-02-1996	AU 1693095 A	14-03-1996
			CA 2197986 A	29-02-1996
			CN 1168625 A	24-12-1997
			EP 0776176 A	04-06-1997
			JP 10507104 T	14-07-1998
			US 5738096 A	14-04-1998
-----				
WO 9315790	A	19-08-1993	US 5354297 A	11-10-1994
			US 5327905 A	12-07-1994
			CA 2117487 A,C	19-08-1993
			EP 0625919 A	30-11-1994
			JP 7504834 T	01-06-1995
			US 5642736 A	01-07-1997
			CN 1082382 A	23-02-1994
-----				